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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,841	01/19/1999	RICHARD G. OLSEN	CIR20013	8242
266 7590 07/17/2006 MUELLER AND SMITH, LPA MUELLER-SMITH BUILDING 7700 RIVERS EDGE DRIVE COLUMBUS, OH 43235			EXAMINER SCHWADRON, RONALD B	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,841

Applicant(s)

OLSEN ET AL.

Examiner

Ron Schwadron, Ph.D.

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ is/are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1. Claims 29-35 are under consideration.
2. The rejection of claims 29-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 29-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Babbitt et al. (US Patent 5,766,920). Applicants arguments have been considered and deemed not persuasive.

Babbitt et al. teach expanded T helper cells from a patient which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing serum free conditioned media (see column 2 and column 3, third paragraph and column 9, first paragraph and column 13). There is no evidence of record that the particular culture conditions recited in the claims would have any particular effect on the treated cells. Babbitt et al. teach that this method can be used to produce cells from HIV patients (see column 7, third complete paragraph). Babbitt et al. teach that mononuclear cells used to derive the expanded cells can be derived from lymph nodes (see column 2, third complete paragraph). Any lymph node cell preparation processed in vitro would be free of cells found in situ other than leukocytes (eg. the in vitro preparation would not contain endothelial cells or other parenchymal cells).

Regarding applicants comments, the instant rejection is not made under 35 USC 103(a) as per applicants comments, but is a rejection under 35 USC 102(e). Regarding the effective date of the Babbitt et al. patent as prior art, said effective date is not the issue date. Applicant is referred to MPEP 706.02(f) which states:

(1). DETERMINE THE APPROPRIATE 35 U.S.C. 102(e) DATE FOR EACH POTENTIAL REFERENCE BY FOLLOWING THE GUIDELINES, EXAMPLES, AND FLOW CHARTS SET FORTH BELOW:

- (A) The potential reference must be a U.S. patent, a U.S. application publication (35 U.S.C. 122(b)) or a WIPO publication of an international application under PCT Article 21(2) in order to apply the reference under 35 U.S.C. 102(e).**
- (B) Determine if the potential reference resulted from, or claimed the benefit of, an international application. If the reference does, go to step (C) below. The 35 U.S.C. 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper benefit claims to prior U.S. applications under 35 U.S.C. 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection in compliance with 35 U.S.C. 112, first paragraph. See MPEP § 2136.02.**

Babbitt et al. teach expanded T helper cells from a patient which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing serum free conditioned media (see column 2 and column 3, third paragraph and column 9, first paragraph and column 13). There is no evidence of record that the particular culture conditions recited in the claims would have any particular effect on the treated cells. Babbitt et al. teach that this method can be used to produce cells from HIV patients (see column 7, third complete paragraph). Babbitt et al. teach that mononuclear cells used to derive the expanded cells can be derived from lymph nodes (see column 2, third complete paragraph). In fact, applicant discloses in page 7, last paragraph of the instant amendment that Babbitt et al. teach that mononuclear cells used to derive the expanded

cells can be derived from lymph nodes. Regarding applicants comments about enablement, both the Examiner and applicant agree that Babbitt et al. teach that mononuclear cells used to derive the expanded cells can be derived from lymph nodes. Any lymph node cell preparation processed in vitro would be free of cells found in situ other than leukocytes (eg. the in vitro preparation would not contain endothelial cells or other parenchymal cells).

Regarding applicants comments about the Triozzi declaration and surprising and unexpected results, as per stated above, the instant rejection is under 35 USC 102(e), not 35 USC 103(a). Therefore, applicants arguments regarding the Triozzi declaration and surprising and unexpected results are irrelevant to the rejection under consideration.

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571 272-0841. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.

Primary Examiner

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RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800-1600